UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

09 CV 0577-S

(PFMJ) PATIENTS FOR MEDICAL JUSTICE

Plaintiff,

-Against-

Defendant.

(CMS) CENTERS FOR MEDICARE & MEDICAID SERVICES

Case No.

COMPLAINT

INTRODUCTION

1. Plaintiff is a director of Patients for Medical Justice (PFMJ) responsible for ferreting out fraudulent Medicare device certifications, reimbursements and defective or non FDA approved medical devices. This is a request for information pursuant to the Freedom of Information Act (FOIA), [5 U.S.C. 552] ("FOIA")] and [31 C.F.R. 1.5. (e)(2)(ii)]. For thirteen months we have been seeking expedited processing of this duplicate request pursuant to [5 U.S.C. 552 (a) (6) (E) (v) (ii)] and [31 CFR 1.5 (e) (2) (ii)]. We are seeking copies of the requested documents.

2. Plaintiff, (PFMJ) Patients For Medical Justice LTD.-James F. Allen, Director brings this action against defendant (CMS) Centers for Medicare & Medicaid Services-Michael S. Marquis, Director, an agency of the United States government, to vindicate PFMJ's right under the Freedom of Information Act ("FOIA"), [5 U.S.C. 552], to obtain, *on an expedited basis*, government records regarding CMS's use of federal funds under the Medicare & Medicaid program. Specifically records relating to the reimbursement of public funds to Guidant Corporation, hospitals, and physicians, for the Ventak Prizm 2DR 1861 "Combination" Biological/Defibrillator manufactured April 16, 2002 through November 13, 2002, illegally placed in United States Commerce July 18, 2002 through December 30, 2003. Product serial numbers 230796 through 243722 (12,926 devices).

3. PFMJ requested records on the subgroup of devices because this subgroup was manufactured, sold and billed to Medicare hospital providers, who, in turn, along with the physicians certified to Medicare, the Federal government, that these devices were "reasonable and necessary" and "safe and effective". However these devices were non FDA Approved devices

that were experimental and investigational. Under the Medicare program for coverage purposes. The term "experimental" has been used synonymously with the term "investigational". Therefore a non FDA approved investigational device serves as an indication that the device was not "reasonable and necessary" within the meaning of the Medicare program. Thus coverage is denied for the devices which are non FDA approved, investigational and without Pre-Market submission or approval. FDA, Office of Device Evaluation (CMS) oversees component and Medicare contractor's compliance to the status and is obligated to offer a customer service to the members of the public including the completion of FOIA requests. [Exhibit K and J].

4. In the third quarter of 2001 (August 9, 2001) a manufacturer of a toxic and carcinogenic biological adhesive, containing formaldehyde, hydrogen cyanide and 7 other chemicals shipped the biological device out of the United States to Clomnel Ireland informing the Food and Drug Administration that the Biological device would not re-enter United States Commerce or be placed inside the human body. The Biological Adhesive was "barred" from United States Commerce and "banned" from internal body use. On July 18, 2002 through November 13, 2002 the investigational, experimental biological adhesive was placed in "Combination" which made a "Brand New" Biological/Defibrillator device and was sold and implanted off labeled, investigational, experimental and non FDA submitted or approved in the United States. [Exhibit Q].

5. On April 16, 2002 through November 13, 2002 two Class III medical devices were placed in "combination" in Clomnel Ireland. Both devices were Non FDA submitted or approved, experimental, investigational, off labeled, adulterated, and misbranded. The addition of the "Combination" Biological/Device was made to the Ventak Prizm 2DR 1861 defibrillators - 12,926 devices. The biological substance had been "barred" from the United States Commerce and "banned" since 1998 by the FDA from being used "inside the human body". The "Combination" Biological/Device contains Synthetic Octyl 2 Cyanoacrylate, formaldehyde, D&C Violet #2 Dye additive, Coal Tar (bituminous coal), Hydrogen Cyanide (asphyxiate), Bisphenol , Phenol, D-n-Octyl Phthalates, 1,4 Benzoquinone, Methyl-Methacrylate Derivates, and Hydroquinone. All chemicals known to be "highly toxic and carcinogenic" and causing Central Nerve Damage. [Exhibit E] [U.S. Patent 6224622].

6. Although the product was cheap there were major disadvantages discovered when the Biological/Device was placed inside the human body. The product was used both as insulation

and adhesive bonding. The 12, 926 devices were then used in a non FDA approved, non FDA supervised human clinical experiment without patient consent or knowledge. The body fluids attacked the adhesive causing rapid disintegration and failure. The Biological Adhesive Device in "combination" was the *Single cause* of the failures of the life sustaining devices. These devices were injected with a non-FDA approved Cyanoacrylate Adhesive April 16, 2002 through November 13, 2002. The Biological product by itself was not FDA approved until January 1, 2003 and then for "Topical Skin Wound Closure Only" not to exceed 30 days of body contact. The "Combination" Biological Device was never FDA submitted or approved for internal body use. [Exhibit E and M]

7. The major disadvantage of cyanoacrylate adhesives is that the degradation created formaldehyde which is toxic and carcinogenic. The chemical leaching entered the surrounding internal body tissue, body fluids and blood circulation system. The rapid degradation of the cyanoacrylate tissue adhesive caused the High Voltage Wire located in the Header Connector Cavity of the defibrillator to become exposed which was one of the reasons the "Combination" Biological/Defibrillator failed. The other reason was the use of the product as a bonding adhesive, placed between the "Plastic Header Shell" and the "Titanium inside wall can" which also rapidly failed. {Exhibit E].

8. Through rapid disintegration and stiffness when cured the Header/Titanium Can combination separated leaving the "Header" dangling at the end of the two heart connected shock leads, both the size of two human hairs, and the non FDA submitted, non FDA approved "Combination" Biological device failed. Because of these known facts cyanoacrylate has never found favor with the FDA for internal body use and, in fact, the manufacturer of the device was warned 1998 through 2009 by the FDA not to use or sell the toxic product for internal human body use. The High Viscosity product was shipped as a experimental, investigational, non FDA approved "Starter Material" to Guidant Corporation, Clomnel Ireland and injected into the Ventak Prizm 2DR 1861 defibrillator devices. Both Class III products were without FDA approval and barred from re-entering United States Commerce, as a "Combination" Biological Device [See Exhibit E & I] European Commission S.I 538/539/540/ the third quarter of 2001 shipment.

9. From December 2007 through March 10, 2008 PFMJ requested a fee waiver [5 U.S.C. 552(a) (4) (A) (i)] effective April 25, 1987]. The waiver was not approved although it was FOIA

law for non-profit LTD's companies. The information from (CMS) Medicare relating to the Guidant sales, Guidant's certification, their billings, the hospital, physicians, Medicare certifications and the reimbursement of federal funds are all available to CMS and are the documents we have requested. From December 2007 through June 13, 2008 the Plaintiff was unsuccessful at getting the information, known to be available, released. The Plaintiff was told to forward a check for the full requested amount. On June 13, 2008, Mr. Michael S. Marquis, the Director of the FOIA group had his secretary inform the Plaintiff that the funds that had been requested in advance, $421.00 dollars, were to be reduced by $215.00 dollars for conducting the research The Defendant provided no information whatsoever and has never returned the balance of $206.00 dollars as stated. [Exhibit (A) (B) and S].

10. The Plaintiff sought expedited processing pursuant to [5 U.S.C. 552 (a) (6) (E)] because of the self-evident importance of the *timely* dissemination of information on these rapidly disintegrating medical devices and the need to warn the remaining 5,000 patients who are still implanted with the "combination" biological devices . The Plaintiff, having been unable to obtain even a timely response to its application for expedited processing as required by [5 U.S.C. 552(a) (6) (E) (ii)-(iii)] and [31 CFR 1.5 (e) (4)]. (PFMJ) is now seeking declaratory and injunctive relief from this Court. [See request dated April 21, 2009] [Exhibit C].

11. The need to provide the public, FDA, and 5,000 remaining patients and their physicians with information contained in the Medicare (CMS) requested records is especially urgent in light of the immediate crisis in the health industry, the lives of the remaining patients and the effect of the $431,000,000 Medicare fraud. Hundreds of millions of dollars paid for Non FDA submitted, non FDA approved, investigational, experimental devices that have caused severe injuries and deaths. This type of criminal behavior, the sale of non Medicare approved devices, is one of the direct causes of the health care industry layoffs and teetering companies struggling to remain solvent. Unprecedented amounts of government capital have been drained from the Medicare program with virtually no government oversight.

12. Given the background and the lack of transparency to date in the government's handling of the non FDA approved, non FDA submitted, Guidant's fraudulent certification and hospital submitted certifications, the Medicare reimbursements, it is imperative that the public be informed promptly about the details of the risks involved with the "Combination" off Labeled Biological devices. (CMS) Medicare has been well informed as this tragedy started in the third

quarter of 2001. These "combination" biological devices have never been FDA filed or FDA approved for internal body use, FDA recalled or Medicare approved for reimbursement yet CMS continues to refuse to abide by the FOIA laws. There has been no public disclosure of the conditions of 12,926 non-consenting, unsuspecting, elderly human beings who have, and will, suffer extreme hardships now and in the future. [Exhibit Q]

13. As the status of the medical manufacturing industry has become increasingly dire there has been widespread recognition of the critical role the public confidence plays in the ability to trust the integrity of these companies. It is self-evident that public confidence depends, in large measure, upon the availability of information about the government's interventions. Likewise, an informed public is essential to the national debate that is currently being conducted in Congress. Accordingly, there is a compelling and immediate need for the documents PFMJ has sought. Plaintiff need not demonstrate that (CMS) Medicare's excuses are totally improper. Rather, (CMS) Medicare has the burden of establishing that they are indeed applicable—something (CMS) Medicare can not and has not done. [See 5 U.S.C. 552 (a) (4) (B)] (Burden is on the agency to sustain its actions); [see also Currie v. I.R.S. 704 F.2d 523 (11th Cir. 1983)]. (holding there is a presumption of disclosures unless, after a de novo review, the agency has carried its burden of proving the withheld materials are within one of the exemptions); [Moorefield v. U.S. Secret Service, 611 F.2d 1021 (5th Cir 1980),] cert denied, [449 U.S. 909] (holding there is a presumption of disclosure and, unless the government proves the information requested falls within a specific statutory exemption, materials must be made available on demand). Therefore PFMJ, James F. Allen Director, has a statutory right to the information the Plaintiffs have requested and there is no legal basis for (CMS) Medicare's refusal to disclose the information in its entirety, without redaction, other than patient and physician names.

JUDISDICTION AND VENUE

14. This district Court has subject matter jurisdiction over this action pursuant to [28 U.S.C. 1331] and [5 U.S.C. 552 (a) (4) (B)]. Venue is proper in this district under [5 U.S.C. 552(a) (4) (B)], because PFMJ's principal place of business lies within this district and Guidant's salesman Mr. James Davis, upon information and belief sold the combination devices to local hospital Medicare providers.

15. The general philosophy of the FOIA is full (CMS) Medicare agency disclosure unless information is exempted under clearly delineated statutory language, which it is not the case in this FOIA request. [*Department of the Air Force v. Rose, 425 U.S. 352,260-61 (1976)]*. The FOIA mandates a policy of broad disclosure of government documents when production is properly requested [5 U.S.C. 552(a) (3)]. The (CMS) Medicare agency may deny disclosure of its records only if the information falls within one of the nine (9) statutory exemptions to the disclosure requirements under [5 U.S.C. 552 (b)]; [Multnomah County Medical Soc'v v.Scott, 825 F.2d 1410, 1413, (9th Cir 1987)]. Inasmuch as (CMS) Medicare under the FOIA has not met its legal duty to respond to PFMJ, James F. Allen Director's request for expendited processing within the required time, PFMJ-James F. Allen Director is relieved of any obligation to exhaust further administrative remedies and is now entitled to appeal directly to the Court to enforce the dictates of FOIA pursuant to [5 U.S.C. 552 (a) (6) (C)].

THE PARTIES

16. PFMJ is a New York State Non Profit LTD company with its principal place of business located at 488 Central Avenue, Suite A, Lancaster, New York. PFMJ is a not for profit LTD Company primarily exposing medical industry patient injustice and fraud.

17. Defendant (CMS) Medicare is a Federal agency within the Department of Health and Human Services of the United States and has possession and control of the records and information that PFMJ is seeking.

BACKGROUND

18. (CMS) Medicare is charged with the primary responsibility of implementing and overseeing the Medicare Reimbursement Program. In 2002 under the Medicare program the American people provided (CMS) Medicare with broad authority to stabilize the financial system of Medicare. In the year 2002 Medicare fell short $48 Billion Dollars in budget overrun. This was the same year that approximately $431,000,000 million dollars was reimbursed by (CMS) Medicare for non FDA approved, investigational, experimental, Ventak Prizm 2DR 1861 "Combination" Biological/Defibrillators, Serial Numbers 230796 through 243722, manufactured April 16, 2002 through November 13, 2002, Guidant Corporation, Clomnel Ireland.

19. Since 2002 there has been mounting concern by both the public and national leaders about the lack of transparency and accountability in (CMS) Medicare program's use of such large quantities of public funds. This concern is evidenced in several ways including (CMS) Medicare's refusal to provide the FOIA information requested, evidence known to have been processed from the manufacturer Guidant, through the hospitals, physicians, and government reimbursed. These were (CMS) Medicare reimbursements consisting of pass through payments to Guidant after being returned to the hospitals, July 18, 2002 through 2003. Federal FDA information (evidence) shows, along with no FDA PMA filing for the "combination/biological/defibrillator" that the devices had never been FDA approved, and therefore considered investigational devices, non Medicare reimbursable. The approximate, fraudulent, reimbursement of $431,000,000 million dollars had been paid for non FDA approved, experimental and investigational devices. During 2002 Congress reported that waste and fraud, in part through incorrect overpayments, had caused Medicare to produce a $48 billion dollar shortfall in funding. [Exhibit L]

20. Accordingly, it is critical to be able to obtain information known to exist in the Medicare system so that the Plaintiff can inform the public, remaining 5,000 patients, physicians, and hospitals how the money is being used and what measures were or were not taken to protect its interests. This FOIA has been narrowed and tailored at (CMS) Medicare's request in meeting their demands, but the refusal to release the documents continues (4 sets of information). Ours is a government of laws including the FOIA laws duly promulgated and laws duly observed. No one is above the law: not the executive, not any federal agency, not the Congress, and not the Judiciary. [ACLU v. Dept of Defense, 339 F. Supp. 2d 501, 502 (S.D.N.Y. September 14 2004) (P&J, 08/30/04)].

21. On or about August 2005 the Plaintiff filed a warning with the FDA about the device and through a long struggle the information was FDA published February 7, 2006 warning of the "high voltage line insulation failure" and "the insulation being destroyed by body fluids"., causing device failures.[Exhibit F].

(PFMJ)-JAMES F. ALLEN DIRECTOR, FOIA REQUEST

22. The Plaintiff narrowed and reduced the request *to four (4) copy sets of Guidant billing submissions from any of the four (4) hospitals listed. Information requested is to include copies of the physician's and hospital's billings and certifications, along with the copies of the Medicare*

reimbursement amounts for those four billing. The documents are to be "non redacted" other than patient and physician names, covering the four (4) Ventak Prizm 2 DR 1861 Defibrillators, implanted July 18, 2002 through 2003, "Serial Numbers ***"Must Be Within"*** *230796 through 243722, along with copies of all Guidant pass through payments and reimbursements[Exhibit C].*

(A) These four (4) hospitals sold and implanted several Ventak Prizm 2 DR 1861 Defibrillators, July 18, 2002 through 2003. These "Combination Devices" were non FDA approved, investigational, biological defibrillator devices. (Reimbursed by Medicare (CMS).

Requested Copies:

Chattanooga Parkridge Medical Center Inc.
2333 McCallie Avenue
Chattanooga, TN 37404
Medicare Provider 440146
Hospital 1-423-698-6061
Billing 1-800-725-8449
Ventak Prizm 2DR 1861- ("Medicare & Medicaid Paid")
Patient Resident of Georgia
*Device implanted January 22, 2003 (Serial Number 24 * 6 * 8)*
*Atrial Lead 4244 (Serial Number 43*7*8)*
*Ventricular Lead 0158 (Serial Number 10*9*3)*
Device Biological Adhesive failed January 12, 2005

Chattanooga Partridge Medical Center Inc.
2333 McCallie Avenue
Chattanooga, TN 37404
Medicare Provider 440146
Hospital 1-423-698-6061
Billing 1-800-725-8449

Ventak Prizm 2DR 1861- ("Medicare"and"Medicaid") Paid
Patient Resident of Georgia
*Device implanted April 16, 2003 (Serial Number 24 * 0 * 4)*
Atrial lead 4244 Serial Number 43 7 * 8*
Ventricular lead 0158 Serial Number 11 4 * 2*
Device Biological Adhesive failed January 12, 2005

The following additional four (4) hospitals sold and implanted the Ventak Prizm 2DR 1861 Serial Numbers 230796 through 243772, July 18, 2002 through 2003, sales that are also found in the (CMS) Medicare files as these Medicare providers notified CMS Medicare of their sales.

Memphis Baptist Memorial East
6019 Walnut Grove
Memphis, TN 38120
Medicare Provider 440049
1-901-226-1400

Johnson City Medical Center
400 North State of Franklin Road
Johnson City, TN 37604-6094
Medicare Provider 440063
1-423-431-6111

St. Thomas Hospital
4220 Harding Road
Nashville, TN 37205
Medicare Provider 440082
1-615-222-6733

Holton Valley Hospital
130 West Ravine Road
Kingsport, TN 37660
Medicare Provider 171319

1-423-230-8200

We are requesting (4) sets of information ***in total*** *from the above hospitals.*

The four (4) examples ***must fall within the Serial Numbers 230796 through 243722,*** and provide ***full and complete information requested per (Number 22) of this filing,*** without redaction other than the patient and physician names. These four implantations with the requested information will complete the FOIA request avoiding further litigation.

(B) Although the Plaintiff, as set forth herein, is in possession of examples of certain documentation relating to the criminal filing for Medicare reimbursement activities complete documentation to support the allegations herein is in the possession and control of (CMS) Medicare. (CMS) Medicare information is far superior to that in possession of the Plaintiff. (CMS) Medicare is mandated both by law and government policy to maintain each and every Ventak Prizm 2DR 1861 Biological "combination" Defibrillator that Medicare reimbursed July 18, 2002 through April 16, 2003, serial numbers 230796 through 243722 (12,926) devices. We are requesting information on four (4) of those devices.

(C) With respect to number (22) of this filing and the (5) hospitals listed above, Guidant Corporation knowingly presented, or caused to be presented, to an officer or employee of the United States Government, one or more false or fraudulent claims for payment and approval of the Ventak Prizm 2DR 1861 Defibrillators manufactured April 16, 2002 through November 13, 2002, marketed and sold July 18, 2002 through 2003, (Serial Numbers 230796 through 243722;

(D) Knowingly made, used, or caused to be made or used by the (5) hospitals, false records or statements to get one or more false and fraudulent Medicare, Ventak Prizm 2DR 1861 "combination" Biological/Defibrillator claims paid or approved by the Government;

(E) Conspired to defraud the Government by getting false and fraudulent Medicare claims allowed, approved and reimbursed; and

(F) other, violations that are Medicare improper, including investigational device payments on non FDA approved devices; in violation of [section 1862 (a) (1) (A)]; "combination"

Biological/Defibrillator; four (4) class III Medical devices, without Pre-Market submission or Pre Market approval.

(G) Upon information and belief, the (5) hospitals filed their paperwork for Medicare reimbursement. The forms included standard language in which the provider certified to the United States government substantially as follows, on the Ventak Prizm 2DR 1861 device subgroup; I certify that I have read the certification statement and that I have examined the accompanying electronically filed or manually submitted cost report... and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider" (Guidant) " in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations" including [42 C.F.R. 413.24 (f) (4) (iv)].

(H) As a direct and proximate result of Guidant's fraudulent and deliberate concealment of the non FDA submitted, non FDA approved, "investigational", "experimental", Ventak Prizm 2DR 1861 "Combination" Biological/Defibrillators, manufactured April 16, 2002 through November 13, 2002, the (5) hospitals listed, along with up to 4,000 additional hospital medical providers were caused to submit Medicare and/or Medicaid reimbursement forms to the Government certifying that the information provided complied with the applicable law when, in fact, certifications were rendered erroneous due to Guidant's false, fraudulent, criminal conduct.

(I) Guidant knowingly and/or recklessly caused these (5) hospitals to submit fraudulent claims to the government for Medicare and Medicaid reimbursement approval of the "Combination" Ventak Prizm 2DR 1861 Biological/Defibrillator. HHS and CMS publish the Medicare Intermediary Manuel [3150] regarding general exclusions from coverage, which states: "Title XVIII of the Social Security Act, [Section 1862 (a) (1) (A)]". "This section *excludes coverage of items or services that are not reasonable and necessary* for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member." (*Toxic and carcinogenic, off labeled, misbranded, adulterated, FDA "barred" from United States Interstate Commerce, FDA "banned" from internal body use, FDA non submitted, FDA unapproved Class III medical devices "combined", are not "reasonable and necessary" for Medicare Coverage.)*

23. Additionally, because of the patent urgency, after a full year of delay, PFMJ - James F. Allen Director, has decided to invoke its rights under the FOIA to seek the requested records for the third time, on an expedited basis, 20 business days. (CMS) Medicare has been improperly denying expedited processing. There were no "unusual circumstances" specifically described in the statute. There has been no "due diligence" used by (CMS) Medicare, in getting the information out to the requester, PFMJ. PFMJ fully complied with (CMS) Medicare's request to narrow the search, fully negotiating and cooperating with (CMS) Medicare; however PFMJ then was informed "that simply reducing the search from 12,926 to (4) four requests, did not mean the request fit the fastest tract."

24. On April 18, 2009, the Plaintiff released a FOIA request directly to New York City because of information received from Washington DC. The Plaintiff was instructed he could avoid the previous (CMS) staff that the plaintiff worked with for over one year and send the request directly to New York, NY. The Plaintiff did so with a clear understanding and instructions not to forward the FOIA request, typed boldly on the front page. [See Exhibit C]. April 24, 2009, in disbelief, the Plaintiff received a letter from Mr. Michael Marquis, the previous (CMS) director the Plaintiff had dealt with over the previous year, stating that we might be able to get the information from New York "if it exists" and "if at any time the estimated costs should exceed $250.00 the office will send you an invoice for the applicable fee with their response". March 10 of 2008 Mr. Marquis refused our first request for a fee wavier, the Defendant then requested an advance of $421.00. After sending the money, the Plaintiff received a letter taking $215.00 for reportedly looking for the information and the Plaintiff received no information [Exhibit D and N] and the refund that was promised in the amount of $206.00 dollars has never been received.

The waiver of all costs pursuant to [5 U.S.C. 522(a)(4)(A)(III)] "(Documents shall be furnished without any charge... if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations and/or activities of the government". The plaintiff feels the contribution to the 5,000 remaining patients implanted, with the non FDA approved toxic devices, their physicians and the FDA is significant by itself.

25. Mr Michael Marquis further stated the Plaintiff should get in touch with a Mr. Paul Velez. The plaintiff contacted Mr. Velez four (4) days later and he stated he had no idea what the Plaintiff was talking about. The Plaintiff faxed the request information. Two (2) days later the

plaintiff contacted Mr. Velez, who promptly stated that he had sent the information back to Baltimore Maryland and Mr. Marquis was going to handle the request. Mr. Velez stated the plaintiff was to contact either Mr. Marquis or Ms. Melodye Hardy. The plaintiff called the following day and left a message for a return call. The call to this day has never been returned. [Exhibit D]

26. This was, and is, the exact pattern of behavior from the first request over one year ago. The Plaintiff ended up speaking with Melodye Hardy, Nicole Moore, Susan Hahn-Reizner, Bernadette McDonald, Emma Gonzalez-Joy, [Exhibit O] commission of civil rights, Gwen Pershing, Vivek Kundra, Lauren Wright, Peter R. Orszag, Dionne Hardy, John Noel, to name a few all with the same answer, they can not deliver the information and Mr. Marquis is in control. Mr. Marquis has continuously refused to return the Plaintiff's phone calls or speak with the Plaintiff. The Plaintiff refuses to be misled for another 12 months and there are 5,000 patients, the FDA and their physicians, who are entitled to the whole story with proof of the violations of Medicare laws and regulations.

27. Mr. Michael Marquis has a pattern of handling the requests in this matter, and further, the Defendant also uses the pattern, even more devastating, by not granting the requests, *"in order to preserve the confidentially of sensitive commercial and government information within (CMS's) possession and control, to protect the effective and efficient operations of the agency"*. The protection of a $431,000,000 million dollar fraudulent (CMS) Medicare pay out of public funds is not information that a criminal court would consider "sensitive commercial government information" and efficient operation in the opinion of the plaintiff, nor are the serious injuries and deaths that were caused in part, as a result of the payout of the $431,000,000 million dollars. [Exhibit (G)]

28. Mr. Michael Marquis' refusal to release the information is nothing more than an abuse of power in violation of the FOIA law, an additional extension and cover-up of the fraud, whether intentional or not, it causes the same effect of discouraging the requester. By using steps of forcing the requester to wait while Mr. Marquis checks with the Attorney General for a "sound legal basis" standard to refuse the request.

29. The real problem is this information is embarrassing to the agency and Mr. Marquis's management of public funds. Mr Marquis has tied up other FOIA requests for as long as *68*

months. (CMS) Medicare did not miss the fraudulent certification submissions "once" in this case, but over 10,000 separate times July 18, 2002 through 2003 , reimbursing, defective, toxic, carcinogenic, off labeled, investigational, experimental, non FDA submitted, non FDA approved, Class III, medical devices totally in violation of Medicare [2300.1];[2303];[2306]; [Category B 2484] and billing requirement (without item 23 of the 1500 submitted); [4122.2] No complete claims processing; no device exemption number; No HCFA Coding; No FDA approval, no human clinical trial, no exempt number in the Master File; *"Medicare is forbidden from paying for "Investigational "Non FDA approved Devices".* [Exhibit (G) (K) and (R)]

(A) *(CMS) Medicare has a "strong history" of paying fraudulent Guidant Corporation billings and the refusal of FOIA requests that relate to the Guidant Corporation itself. The Freedom of Information Act by law should be administered with a clear presumption: In the face of doubt, openness prevails. CMS should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears. CMS responding to requests under the FOIA, an executive branch agency, should act promptly and in a sprit of cooperation. Executive Order 13392, the President of the United States, Barack Obama, Director of the Office of Management and Budget Mr. Peter Orszag ,and Mr. Eric Holder. (Disclosure should be timely).*

(B) One hospital that would provide the FOIA information the Plaintiff has requested, in the event that (CMS) Medicare is still unable to find any of the 10,000 plus fraudulently certified, non FDA approved, investigational, (CMS) Medicare filed reimbursements is Saint Thomas Hospital ("St Thomas") in Nashville, Tennessee, Hamilton County Authority d/b/a/ Erlanger Health System Hospital ("Erlanger") in Chattanooga, Tennessee or Tri-star hospital formerly Columbia/Hospital Corporation of America to mention just two (2). Guidant not only caused these hospitals to file fraudulent claims but defrauded federal and state Medicare and Medicaid programs by causing the hospital to submit certified claims for "investigational" non FDA approved Ventak Prizm 2DR 1861 Defibrillators. Guidant willfully and intentionally concealed the Non FDA approved "Combination" Biological/Defibrillators.

(C) Surgeons, cardiovascular surgeons, cardiologists and electrophysiologist implanted the Ventak 1861 device models, July 18, 2002 through 2003, in both of these hospitals under the Medicare (CMS) reimbursement programs. These hospitals paid for the devices to Guidant or the product was kept on consignment in storage in these hospitals to be reimbursed by the United

States Medicare and Medicaid programs. Even during 2002 for the "pass through" Ventak 1861 device (CMS) paid additional amounts while it gathered data on the cost of the procedures for this subgroup of devices, paying out federal dollars for unqualified fraudulent devices. Although the calculation of IPPS and OPPS, DRG and APC reimbursements has varied through the years 1981 through 2003, the cost of the Ventak Prizm 2DR 1861 devices sold July 18, 2002 through 2003 was included in the formulae. The costs were a major factor used as a basis to establish Medicare reimbursements to provider hospitals for both implantation and subsequent replacement for device failures.

(D) The government (CMS) Medicare, relying on the accuracy of the certified reports, calculated the basis of reimbursement for inpatient and outpatient services based on fraudulent non qualified devices. The physicians made the decision to purchase Guidant's Ventak Prizm 2DR 1861 devices and the hospitals made the fraudulent certification and submission to Medicare. The doctors also demanded that the hospitals keep the devices in storage and available. Guidant was fully aware of the sale of the off labeled, investigational, non FDA submitted, non FDA approved, toxic and carcinogenic Ventak Prizm 2DR 1861 "Combination" Biological/Defibrillators and that the devices resulted in improper Medical Cost Reimbursements by Federal and State agencies in the hundreds of millions of dollars. Seventy Eight (78%) of the 12,926 defibrillators subgroup that were sold, submitted and reimbursed by Medicare (CMS), approximately $431,000,000 million dollars, for non FDA approved and "investigational" devices.

(E) Both St. Thomas, Erlanger, Nashville, TN. 37205, phone (615) 222-6604 and Tri Star Health System Greenview Regional Hospital, Nashville, TN 37201 Phone (270) 793-1000 were caused to submit fraudulent certifications by the intentional, knowing, reckless and deceptive concealment by Guidant of the reimbursements for investigational, non FDA approved defibrillators.

(F) With each of these implants Guidant was provided with a copy of a standardized report *("registration form")*, which was addressed to Guidant in a postage prepaid envelope. This report identified the patient by name, address, Social Security Number, date of birth, *the implanting health care facility, the implanting doctor, the following physician, the referring physician, the date of the procedure, the implanted or replacement medical device (by model and serial numbers), the implant leads used (by model and serial numbers), the positions of the*

implanted leads, the date of implant for both the acute and chronically placed leads), (by model, serial number and date of implant,), the removed device (by model and serial number), the explanted pulse generator (by model, serial number and date of explant) and any leads removed (by model, serial number, the date removed, the sales agent, who obtained the purchase order data (serial number, billing prices paid, etc.) from the hospital for the Ventak Prizm 2DR 1861 sold on consignment. All data was relayed to Guidant. Guidant then billed the hospitals, collected the charge for the Ventak Prizm 2DR 1861 July 18, 2002 through 2003, and paid the salesman's commission. *Tracking information during the relevant times herein was forwarded to HHS* and/or the FDA. Guidant would then send another device to the hospital.

(G) Guidant, by knowingly concealing that the Ventak Prizm 2DR 1861 "Combination" Biological/Defibrillators were non FDA submitted, non FDA approved, "investigational", "combination" Biological/defibrillators caused the hospitals across the country to present to the government fraudulent certifications for reimbursements of the defibrillators and paid Guidant Corporation for the off labeled, adulterated devices. The *hospitals sought and received* Medicare and Medicaid payments submitted on standardized forms to Medicare from which the Medicare reimbursements were calculated. These forms contained fraudulent information related to the cost and requirement for the devices. This false data along with others was used to calculate reimbursement for DRG procedures including without limitation DRG 118 and DRG 515 procedures nationwide and to calculate outpatient reimbursement nationwide. Guidant's concealment of the non FDA approved devices from the hospitals and physicians caused the hospitals to submit the fraudulent Medicare and state and federal Medicaid filings.

(G) On information and belief, Guidant knew or should have known that the concealment of the defibrillator/biological "combination", non FDA submitted, non FDA approved, investigational, devices would be submitted to Medicare and Medicaid cost reports that improperly included the devices as a reimbursable expense. Guidant had provided detailed instruction to medical providers interpreting Medicare Reimbursement. and recommending how to bill Medicare providers interpreting the Ventak Prizm 2DR 1861 2002 subgroup guidelines and recommending how to bill Medicare costs, of the *unqualified* devices.

(H) Guidant sales representatives attending these implant procedures would entered the computerized information, including the reason for the replacement, into Guidant's internal information system. As a direct result of the "Free" device, thereupon Medicare reimbursement

was applied for the expenses, including the full cost of the replacement device, which Guidant had supplied at no cost to the hospitals.

Medicare paid approximately for the "newly implanted device"	$11,870.00	under C-1785
Medicare paid approximately for the "Hospital Cost"	6,190.00	
Medicare paid approximately "Physician Removal Cost"	3,721.00	
Totaling approximately	$21,781.00 to $23,750.00	

(I) Guidant not only avoided *any* cost arising from the replacement, they profited for the second time off one patient, approximately $11,870.00 dollars and the company was directly responsible for selling Non FDA approved "combination" biological devices in which the non FDA submitted, non FDA approved "Biological Adhesive Combination" was the direct cause of the device failures.

30. On April 21, 2009 the Plaintiff requested, for the second time, after a full year of total denials, using the "FOIA, right to request Expedited Processing again". The request was explicit as was the full year of communications, in detailing the urgencies of complying with the FOIA regulations. The 5,000 patients, further heart damage, additional surgeries, poisonings, deaths, leaching chemicals, toxicity, carcinogens, and the FDA "barring" of the product from United States Commerce and "banning" of internal body use was clearly elaborated in all communications. [Exhibit (C)].

31. The second effort on the part of the Plaintiff was stimulated because of a communication from Washington DC that all federal agencies were no longer abusing the federal FOIA, that the plaintiff could send the request to a separate regional administrator in New York State who would provide the results needed and that the Plaintiff would no longer be forced to deal with Mr. Michael Marquis, Director, who for 12 months+ led the effort in refusing to ferret out the information, known by (CMS) Medicare regulation to exist. On one occasion June 13, 2008, Mr Marquis had previously instructed the Plaintiff to forward an advance payment of $421.00 dollars for the information and then returned a letter stating that $215.00 dollars was used for the cost of the research and $206.00 was being returned. The $206.00 was never returned and there was no fulfillment of the requested information. [Exhibit B].

32. The following information from the Government had been supplied to Mr. Marquis and the (CMS) Medicare staff, no later than February 1, 2009 with instructions to provide the FOIA information. Stating the following:

> "The Freedom of Information Act should be administered with a clear presumption, in the face of doubt, openness prevails." "The Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears." "In responding to requests under the FOIA, executive branch agencies (agencies) should act promptly and in a spirit of cooperation, recognizing that such agencies are servants of the public." "All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in the FOIA, and to usher in a new era of open Government and citizenry alike." "The presumption of disclosure should be applied to all decisions involving FOIA." "The presumption of disclosure also means that agencies should take affirmative steps to make information public." "Disclosure should be timely." *"Executive Order 13392"* [Exhibit H].
>
> Barack Obama

(CMS), Medicare, and Mr. Michael Marquis, have refused to make the presumption of "openness" a reality, ordered by the President of the United States. The process to provide information can *not* be accomplished without rigorous ferreting out of the request. The 5,000 patients still do not have any knowledge of what is transpiring inside their bodies, nor does the public have any idea that approximately $431,000,000 dollars of their funds has been fraudulently certified and improperly reimbursed by (CMS) Medicare. The requested information is held for a fact by Medicare, the physicians, hospitals, and Guidant. There are three key points that are being missed by (CMS), Medicare, and Mr. Michael Marquis.

those officials are daily being asked to make critical and sweeping decisions based on limited information on the Medicare program. Significantly, any delay will further undermine public confidence in the integrity and reliability of (CMS) Medicare further eroding the American financial system.

42. In addition to the foregoing PFMJ's payment of $421.00 in fees resulted in not one page of the information requested being returned. The Plaintiff has narrowed the search to (4) sets on (4) defibrillators out of the 12,926 devices. *The Plaintiff respectfully requests a full and immediate refund of the payment made to CMS in the amount of $421.00 dollars made payable to Myers, Quinn, and Schwartz LLP, and no further billings for the four(4) sets of information being sought in this filing.*

43. With respect to (CMS) Medicare's non-granting or granting of the information, expedited processing, and attempting to drag out the second filing *that process expired on May 21, 2009,* the second attempt at filing, after the full year of waiting the Plaintiff can no longer allow the need for the information to be disregarded an additional 13 months, Pursuant to [5 U.S.C. 552(a) (6) (E) (ii) (I)].

44. As of the date of this complaint (CMS) Medicare has not responded to PFMJ's 2nd FOIA application for expedited (20) business day processing, other then telling the Plaintiff about more fees and *"if information exists"*. That statement *"if information exists" infers* the information does not exist, which would indicate CMS Medicare played a part in conspiring to reimburse thousands of fraudulent claims. The information requested by the Plaintiff must be submitted to the agency and kept on file. The agency can not reimburse the hospitals and, in turn, Guidant in making $431,000,000 million dollars in known fraudulent payments without the information of who was paid, how much, and for what. Rather than ruling on the expedited-processing requests (CMS) Medicare, Mr Michael Marquis, merely supplies letters confirming the substance of PFMJ's request but says nothing about the request for expedited processing. To date (CMS) Medicare has not taken any steps in response to PFMJ in terms of discussing a timely scope of its compliance, with a full knowledge of the remaining 5,000 patients in harms way. The Plaintiff has already foolishly waited a full year only to be informed, "there were no records," when in fact it is known the information and records do exist in the Medicare system. It is up to (CMS) Medicare to ferret out those four (4) sets of information, and respectfully, if all 10,000 plus of those records have been misplaced than (CMS) Medicare can contact any four of

the 4,300 Medicare provider hospitals that certified and billed for the devices July 18, 2002 through 2003 requiring them to send their copies of Guidant's billings and certification, hospital certifications, reimbursement copies, for the physician, hospital and all pass through payments made to Guidant Corporation for the Ventak Prizm 2DR 1861 implantations, July 18, 2002 through 2003.

FACTS

45. (CMS) Medicare failed to conduct an adequate search for documents that are known to exist regarding the Ventak Prizm 2 DR 1861 Defibrillators implanted July 18, 2002 through 2003. Guidant, the manufacturer, shows total sales of 12,926 devices in the subgroup and of that number approximately (78%) were Medicare sales or 10,000 plus were Medicare governmental reimbursements.

46. In response to PFMJ's FOIA filing (CMS) Medicare has stated there were no records of the filings. Guidant, the manufacturer, operates under national Medicare coverage for the devices. The devices were stored on consignment at the various Medicare provider hospitals and physicians providers who certified and billed the Medicare Program. The reimbursement payments to Guidant were passed through by the hospital for Guidant's "Combination Biological device, and leads. The hospitals certified to (CMS) Medicare that all of the devices were FDA approved. Those actions by Guidant, the physician, and hospitals contain the plaintiff's *material information requested, in CMS Medicare system, whether paper or electronic.*

47. Data must be collected and reported through an approved data collection mechanism for the (CMS) Medicare patients to receive a defibrillation implant. The data information requested reported both a completed human clinical trial, PMA FDA approval, the patient must be able to provide informed consent, and CMS must maintain an implantable automatic defibrillator registry using the same mechanism the Medicare hospitals already use. None of these three (3) requirements were completed or met for the Medicare coverage on the 10,000+ devices themselves, but the records state fraudulently that the requirements were met and the plaintiff is respectfully requesting copies of those three requirements included with the four (4) sets of Combination defibrillator information.

48. (CMS) Hospital providers billing Medicare FLs use G Codes (Payable under OPPS effective October 2003 GO297, GO298, GO299 and GO300. Medicare was supplying the data collection forms for the hospitals to fill out.

49. These Medicare filings had to provide specific material facts and information in justification of a genuine issue of material fact and need for the Ventak Prizm 2DR 1861 Biological "Combination" Defibrillator billing, hospital certification, physician billing and pass through Guidant payment information requested, from (CMS) an ("Agency") within the meaning of [5 U.S.C. 551(1) and 701(b)(1)].

FIRST CAUSE OF ACTION

50. *(Violation of the Freedom of Information Act for improper withholding of known, agency records) [5 U.S.C. 552(a) (3) (A)]; and [5 U.S.C. 552 (a) (3) (A), (4) (B)].*

The agency is required "to make a good faith effort to conduct a search for the requested records, using methods that can reasonably produce the documents". ["Oglesby, 920 F 2d at 68]. " Because the agency is in possession of the records and is responsible for conducting the search the Court may rely on "[a] reasonably detailed affidavit, setting forth the search terms, the type of search performed, and averring that all files likely to contain responsive materials (if such records exist) were searched." [Valencia-Lucena, 180 F3d at 326] [quoting Oglesby, 920 F. 2d at 68]. Summary judgement is inappropriate "if a review of the records raises substantial doubt" about the adequacy of the search.

Plaintiff, on information and belief states that (CMS) Medicare did not include copies of the Guidant billings, Guidant certification, hospital certifications, Hospital (CMS) Medicare billings, Physician (CMS) Medicare billings, (CMS) Medicare reimbursements, all pass through hospital payments to Guidant Corporation July 18, 2002 through 2003, on the four (4) devices requested. Serial Numbers 230796 through 243722, approximately (10,000) non FDA approved Ventak Prizm 2 DR 1861 devices, paper and electronic files, for the (4) devices requested, were not provided in CMS's effort to accumulate the proper information. (All Federal Documents known to be stored within the CMS system.)

51. PFMJ – James F. Allen Director repeats and alleges all the allegations contained in paragraphs 1-50 as if fully set forth.

52. The documents requested by PFMJ's FOIA request constitute agency records subject to mandatory disclosure under the FOIA. [Executive Order 13392 (December 2005)]-requires Federal Agencies (CMS) Medicare, to make their FOIA program "citizen-centered and result-oriented". The PFMJ information FOIA request is *not* exempt from mandatory disclosure. (CMS) in administering the Act must not overlook their obligation to focus on individual records that require disclosure meeting the act's primary objective of "maximum responsible disclosure of government information" [FOIA Update Vol. XIV, No. 3 (1993)] OIP Guidance.

53. (CMS) Medicare has improperly withheld the requested agency records from (PFMJ), in violation of [5 U.S.C. 552(a) (3) (A)]...

SECOND CAUSE OF ACTION

54. *(For a Declaration that PFMJ-James F. Allen Director is entitled to expedient processing of the FOIA Request). (20 Business days)*

55. (PFMJ) – James F. Allen Director repeats and realleges all of the allegations contained in paragraphs 1-54 as if fully set forth.

56. (PFMJ) is primarily engaged in the exposure and dissemination of information to the patients that are harmed, the FDA and the public, as referred to in [31 CFR 1.5(e) (2) (ii)].

57. There exists compelling need(s), and an urgency to inform the 5,000 patients, the public, and the FDA about the information sought in the (PFMJ's), FOIA request as is required by [5 U.S.C. (a) (6) (E)], without success in acquiring the FOIA known materials.

58. (PFMJ) has complied with all efforts with respect to the substantive and procedural rules governing request for records under FOIA as required by [5 U.S.C. 552(a) (3).]

59. As a result of (CMS) Medicare's failure to meet its statutory deadlines under [5 U.S.C. 552 (a) (6)(E)(ii)(I)], (PFMJ)-James F. Allen Director has deemed to have totally exhausted its administrative remedies pursuant to [5 U.S.C. 552 (a)(6)(C)(i)].

60. An actual and justifiable controversy exists as to whether (CMS) Medicare has violated the FOIA by failing to grant (PFMJ), for a 13 month period of time, expedited processing and the delivery of known information, used in the processing of each of Guidant's certifications, Guidant's billings, physician billings, hospital certification billings and Medicare reimbursements. (PFMJ) is deemed to have totally exhausted its administrative remedies pursuant to its FOIA requests.

61. As a result of the foregoing, (PFMJ) is entitled to a declaration that its FOIA requests be afforded expedited processing, within 20 business days.

THIRD CAUSE OF ACTION

(For an Injunction Compelling Expedited Processing)

62. (PFMJ) repeats and realleges all of the allegations contained in paragraph 1-61 as if fully set forth herein.

63. As a result of the foregoing, (PFMJ) is entitled to an injunction compelling (CMS) Medicare to afford its FOIA requests expedited processing, within 20 business days.

FORTH CAUSE OF ACTION

(For a Declaration that (PFMJ) is Entitled to the Records Sought in Its Request)

64. (PFMJ) repeats and realleges all of the allegations contained in paragraphs 1-63 as if fully set forth herein.

65. Upon information and belief, the records sought in the (PFMJ's) FOIA request are in the custody and control of (CMS) Medicare. These documents were established July 18, 2002 through 2003, including Guidant Corporation's billings, Guidant Corporation certification,

physician billings, hospital certifications and billings, (CMS) Medicare submissions and reimbursements, all hospital pass through Guidant payments, on the Ventak Prizm 2 DR 1861 "Combination" Biological " devices.(Approximately 10,000, non FDA approved, investigational devices. July 18, 2002 through 2003 implants.)

66. Upon information and belief, the records sought in (PFMJ's) FOIA request are "reasonably described" as required by [5 U.S.C. 552 (a) (3)] and the description is with sufficient particularity to permit the conduct of an organized, non random search, narrowed to four (4) sets of information (examples), out of an approximately 10,000 sets available, in CMS possessed, Medicare files. The document information includes more than sufficient file-related information (type of document, title names, and product name, product manufacturer's name, the dated period of Guidant's wholesale to the hospitals, subject area, and date of creation, originator, and circumstances surrounding the events the records covered).

67. Upon information and belief, the records sought in PFMJ's request are not subject to any of the exemptions from public disclosure that are set forth in [5 U.S.C. 552 (b)].

68. An actual and justifiable controversy exists in that (CMS) Medicare has failed to disclose known records, held by CMS, sought in (PFMJ's) FOIA request.

69. As a result of the foregoing,(PFMJ) is entitled to a declaration that (CMS) Medicare is obligated to provide the Plaintiffs with copies of the records sought in (PFMJ's) FOIA request.

On information and belief Plaintiff has found that (CMS's) assertion that the specific information requested is non existent, contains an averment or assertion suggesting that a search for responsive records was undertaken for 12 months in all locations and (CMS) Medicare systems of records likely to contain documents responsive to the Plaintiff's FOIA request. The defendant by law must totally maintain the Plaintiff's requested information and documents in order to have reimbursed the fraudulent claims.

On information and belief the Defendant has to date refused to perform an adequate search of all records systems and record locations which contain this type of agency records and documents responsive to the FOIA request. ***Further, the Defendant, in stating the records requested are***

non existent; is stating that the supplier Guidant was paid approximately $431,000,000 million tax payer dollars without billing the Medicare provider hospitals; that Guidant was reimbursed with federal funds without device certifications; that Guidant's billings for reimbursement from the hospitals were not submitted to Medicare; that the physicians were Medicare paid without billings; and that 10,000 Medicare patients were implanted with a non FDA approved Ventak Prizm 2DR 1861 investigational and "experimenta" "Combination" Defibrillator", used without consent in a Non FDA approved, non FDA supervised, human clinical trail" *without being accounted for by the manufacturer, hospital, physician, or Medicare (CMS), July 18, 2002 through 2003. (Serial numbers 230796 through 243722.)*

FIFTH CAUSE OF ACTION

70. (FOIA) [5 U.S.C. 552] [Public Law 104-231] OIG, OAS reports are made available to the public) [See 45 CFR Parts 5.]

71 U.S. Department of Health and Human Services (HHS), Office of Audit Services (OAS) Office of the Inspector General (OIG) entitled *"Review of Medicare Transitional Pass-through Payments"*, made under the Hospital Outpatient Prospective Payment System for Drugs, Biological, and "Combination" Biological Medical Devices implanted at the hospitals. Medicare has used several billing and payment systems that have evolved over the years since on or about 1981: (1) cost- based reimbursement; (2) the Inpatient Prospective Payment System ("IPPS") for certain in patient hospital services, and (3) the Outpatient Prospective Payment ("OPPS") for certain outpatient hospital services. Depending on the complexity of the procedures doctors have used both inpatient and outpatient filings, and since 1983 Medicare paid pre-determined rates or ("DRG's). In 2002 the Ventak Prism 2DR 1861 Non-FDA approved devices were paid, under the ("OPPS") system.

72. July 16 2002 through 2003, the Centers for Medicare and Medicaid Services (CMS) operated under a payment system for hospital outpatient services (OPPS), including the implantation of the Guidant, Ventak Prizm 2DR 1861 Non FDA Submitted, "Combination" Biological Defibrillators. The Balanced Budget Act of 1997 amended [section 1833 (t)] of the Social Security Act (the Act) authorizing the implementation of (OPPS). Congress enacted major changes to OPPS, which provided "transitional pass-through payments" for the biological/defibrillator, for Medicare Patients. For devices, such as the "Combination"

Biological/Defibrillator Ventak Prizm 2DR 1861, the pass-through payment equaled the amount by which the hospital's charged, adjusted to cost, exceeded the OPPS payment rate associated with the defibrillator.

73. (CMS) Medicare used the National Claims History file to identify pass-through payments made to the hospitals, and reviewed applicable CMS Program Memoranda to determine the eligibility of sample biological and medical devices (Defibrillators). Medicare would review the hospital's itemized bills, Medicare UB-92 claim forms, (CMS) Medicare paid the claims, to ensure the items were billed appropriately and the costs paid correctly by (CMS) Medicare.

74. This CMS Medicare process was available to the agency at any time they chose to review the pass through payments, based on billing records. (CMS) Medicare did not review the medical records to verify that items were actually provided and/or were medically necessary and appropriate, with the Ventak Prizm 2DR 1861 "Combination" Biological/Defibrillators. Had PMA FDA records been checked the device's addition of the biological Adhesive, in "Combination" made the payment of Medicare dollars (public funds) totally illegal and the certifications provided to (CMS) from the hospitals/physicians fraudulent.

75. Usually (CMS) Medicare reviews are limited to the internal control structure of those controls concerning the accumulation of charges, creation of outpatient bills and submission of Medicare Claims because the usual objective of these reviews did not require an understanding or assessment of the complete internal control structure at the hospitals.

76. All of these charges and information the Plaintiff has FOIA requested are held by (CMS) Medicare. (CMS) demands that the charges are broken down for each medical supplied device associated with the "eligible" Biological and defibrillator "Combination" device, for the Guidant transitional pass-through payments.

77. The Ventak Prizm 2DR 1861 Defibrillator "Combination" Biological Defibrillator Device system included a pulse generator containing electronics, battery and two electrodes (Leads) attached to the patient's heart and the device. Using (CMS) [HCPCS code 33208] the devices are inserted or replaced with the so called permanent Defibrillators (1861 Model), with Transvenous electrodes(s); atrial and ventricular. (CMS) Medicare should have never made the decision to allow a reimbursement of any transitional pass-through payments for the devices.

These "Combination Biological/Defibrillator Devices" were non FDA submitted, non FDA approved, investigational, experimental devices, implanted without patient consent, being used in a non FDA unsupervised human clinical trial, in 12,926 heart damaged patients without consent or their knowledge.

78. These "Combination" Biological/Defibrillator devices" were not eligible for the Medicare program and were fraudulently and incorrectly coded. In accordance with the principles of the Freedom of Information Act [5 U.S.C. 552], and the known facts that (CMS) Medicare controls the requested information, [Public Law 104-231], the documents should have been released. (CMS) Medicare reports issued are to be made available to members of the public and PFMJ - James F. Allen requested same without redaction other than personal names. [Exhibit (S) (A) (B) (C)]. (CMS) knowingly withheld the requested information and documents, known to be part of CMS Medicare files by law, stating the information was non existent.

79. January 31, 2002, in accordance with the principles of the Freedom of Information Act [5 U.S.C. 552], as amended by [Public Law 104-231], OIG OAS reports issued are to be made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. [See 45 CFR Parts 5.]

PRAYER FOR RELIEF

80. **WHEREFORE**, (PFMJ)-James F. Allen Director prays that this Court:

(A) Declare that (PFMJ)-James F. Allen's FOIA request is entitled to receive expedited processing within the 20 business days;

(B) Issue an injunction compelling (CMS) Medicare to provide with (PFMJ)-James F. Allen's FOIA request expedited processing within 20 business days;

(C) Declare that (PFMJ) James F. Allen is entitled to copies of the records sought in its FOIA request without redaction, other than the patient's and physician's name;

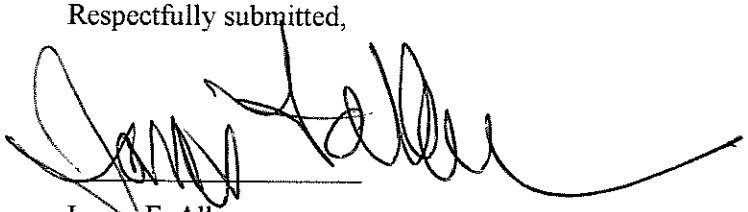
(D) Issue an injunction compelling (CMS) Medicare to collect and give to (PFMJ)-James F. Allen all copies of the four (4) sets of records requested in the FOIA request;

(E) issue an injunction that the four (4) sets of records (copied) paper or electronic, requested will contain the hospital name, Guidant's billing submission to that hospitals, the physician's billing, the serial numbers of the four (4) devices in the 230796 through 243722 subgroup, the date of implant July 18, 2002 through 2003, the hospital certifications, (CMS) Medicare submissions that were made, the Medicare hospital reimbursement, all pass through payments, showing individual and total amounts, and the hospital billings and payments made to Guidant Corporation;

(F) Issue an injunction for the refund of a previous over charge of $421.00, check to be made payable to Myers, Quinn & Schwartz, Attorneys at Law, 5500 Main Street Suite 312, Williamsville New York 14221 [Exhibit (A) & (B)];

(G) Award (PFMJ)-James F, Allen reasonable attorney fees and other litigation costs under [5 U.S.C. 552 (a) (4) (E) (i) (ii)]; and [5 U.S.C. 552 (a) (4) (E)] as amended by the Openness Promotes Effectiveness in our National Government Act 2007, [Pub. L. No. 110-175 4,]; [121 Stat. 2524, 2525] and; (H) Grant such other and further relief as the Court deems just and proper.

Respectfully submitted,



Dated June 23 2009

James F. Allen
Patients for Medical Justice
488 Central Avenue
Buffalo, New York 14086
1-716-685-2918